

In re: Conkling et al.
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Filed: August 28, 2001
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REMARKS

The Office Action dated April 13, 2004, has been received and reviewed. Claims 1 and 4-32 are pending in the present application. Claims 33-73 have been withdrawn from consideration and have now been canceled without prejudice or disclaimer. Claims 1-32 stand rejected. Claims 11-32 have been canceled without prejudice or disclaimer with respect to filing a continuation application. Applicants have added new claims 74-85. Applicants respectfully request reconsideration of the application in view of the amendments to the claims and the arguments below.

Applicants note that they have amended the title of the invention to be indicative of the invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objections to the title.

I. Claim Amendments

Claim 1 has been amended to better state that which is the invention and to correct minor informalities. Claim 8 has been amended to correct for minor informalities. Claims 11-73 have been canceled without prejudice or disclaimer. Claims 74-85 have been added. Support for these amendments can be found throughout the specification, examples and figures of the present application and as noted in this response.

II. Claim Objections

Claims 8 and 13 stand objected to for minor informalities. Applicants have corrected these informalities to Claim 8 as suggested by the Examiner. Applicants have cancelled Claim 13 without prejudice or disclaimer thus mooting this objection. Accordingly, Applicants respectfully request that the objections to Claim 8 be withdrawn.

III. Rejections under 35 U.S.C. § 112, first paragraph

A. Enablement

Claims 1 and 4-32 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in

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such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, to make and/or use the invention commensurate with the scope of the claims. As Applicants have cancelled Claims 11-32 without prejudice or disclaimer they will focus their arguments on the remaining claims. Applicants note that they respectfully traverse the rejections to Claims 1 and 4-10.

The Office Action alleges that Claims 1 and 4-10 do not provide enablement for 200 nucleotide fragments of SEQ ID NO: 1 or active fragments. Applicants respectfully disagree with this assertion, but in the interests of speeding prosecution of the remaining claims, Applicants have amended Claim 1 to recite "An isolated nucleic acid comprising the isolated nucleic acid sequence of SEQ ID NO: 1 operably linked to a *Nic* gene product." Applicants note that the specification recites on page 4, lines 10-12 recites one example of the embodiments of the present invention is a *Nic* gene product responsive element (e.g., a DNA sequence that binds to a *Nic* gene product) such as SEQ ID NO: 1. Furthermore on page 11, lines 13-18 note that "in some embodiments, the embodied nucleic acids have a structure that promotes an interaction with one or more transcription factors (e.g., *Nic1* and *Nic2*), which are involved in initiating transcription of QPTase and/or PMTase. Accordingly, said nucleic acids are said to be or contain at least one transcription factor (e.g., *Nic1* and *Nic2*) binding sequences, which are also referred to as "cis-acting regulatory elements." Accordingly, Applicants submit that amended Claim 1, and its subsequent dependent claims, Claims 4-10, are enabled. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph rejections to Claims 1 and 4-10.

Applicants further submit that Claim 74 finds support for producing transgenic plants on page 13, lines 20-25, page 14, lines 16-24, page 19 line 21 to page 21 line 20, example 2, and throughout the application.

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Claim 75 finds support on page 11, lines 13-21 which define the *Nic* gene product.

Claim 76 finds support on page 18, lines 4-8. Furthermore, the specification recites that "determinations of sequence similarity are made with the two sequences aligned for maximum matching; gaps in either of the two sequences being matched are allowed in maximizing matching. Gap lengths of 10 or less are preferred, gap lengths of 5 or less are more preferred, and gap lengths of 2 or less still more preferred." Additionally, the specification states "'slight and non-consequential sequence variations' mean that 'similar' sequences (i.e., the sequences that have substantial sequence similarity with the DNA, RNA, or proteins disclosed and claimed herein) will be functionally equivalent to the sequences disclosed and claimed in the present invention." Thus, one of skill in the art could readily ascertain that deletions, insertion and mutations in the sequence are possible without effecting the functional equivalent of SEQ ID NO: 1.

Additionally, Claims 77-85 are supported by the as filed specification for the same reasons as Claims 1 and 4-10 as these claims are directed to sequences that consist of SEQ ID NO: 1.

Accordingly, Applicants respectfully ask for reconsideration and withdrawal of the rejection to Claims 1 and 4-10 and for the allowance of Claims 74-85.

B. Written Description

Claims 1-32 are also rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. Applicants respectfully disagree with this assertion. Additionally, because Applicants have cancelled Claims 11-32 without prejudice or disclaimer they will focus their arguments on the remaining claims.

Applicants note that the U.S.P.T.O. has clarified the standard for examining applications for compliance with respect to the written description requirement of 35 U.S.C. §112, first paragraph. These guidelines state, in part:

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The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed Consequently, rejection of an original claim for lack of written description should be rare.

(Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1105 (Jan. 5, 2001); emphasis added).

Applicants respectfully contend that the specification does provide a sufficient written description so that one skilled in the art would appreciate that the Applicants were in possession of the claimed invention at the time of filing. However, in an effort to expedite the present claims, as noted above, Applicants have amended Claim 1 to recite SEQ ID NO: 1. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph to Claims 1 and 4-10.

IV. Rejections under 35 U.S.C. § 112, second paragraph

Claims 5-9 and 14-31 stand rejected under 35 U.S.C. § 112, second paragraph for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. As Applicants have cancelled Claims 14-32 without prejudice or disclaimer they will focus their arguments on the remaining claims. Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejections in view of the claim amendments and the following remarks.

Claim 5 has been amended as suggested by the Examiner. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections to Claim 5. As a result of the amendment to Claim 5, Applicants submit that Claims 6-7 and 9 now have proper antecedent basis. Accordingly Applicants respectfully request withdrawal of the rejections to these claims. Applicants have also amended Claim 8

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for proper antecedent basis. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections to Claim 8.

V. Rejections under 35 U.S.C. § 102(b)

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Conkling et al., WO 97/05261. Applicants respectfully traverse this rejection for the reasons set forth below.

Case law holds and the M.P.E.P. states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). WO 97/05261 fails to disclose the subject matter contained in Claims 1-10.

Applicants note that amended Claim 1, of which claims 4-10 depend from, recites, "An isolated nucleic acid comprising the isolated nucleic acid sequence of SEQ ID NO: 1 operably linked to a *Nic* gene product." Applicants submit that WO 97/05261 fails to disclose such an isolated nucleic acid. Therefore, WO 97/05261 fails to anticipate Claims 1 and 4-10 of the present application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102(b) rejections to Claims 1 and 4-10.

VI. Double Patenting

Claims 1 and 4-10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 16-22 of U.S. Patent No. 5,837,876. Applicants respectfully disagree with this assertion. Applicants note that with respect to the double patenting rejections based on 35 U.S.C. § 101, M.P.E.P. § 804 provides:

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A reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent [or related pending patent application]. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there were such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.

Applicants note that the sequence claimed in Claim 1 of the present application is not the same as SEQ ID NO. 1 of U.S. Patent No. 5,837,876. Furthermore, the pending claims are not obvious in view of the claims of U.S. Patent No. 5,837,876. Accordingly, Applicants submit that Claims 1 and 4-10 are patentably distinct from U.S. Patent No. 5,837,876, thus mooted this rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the nonstatutory double patenting rejection.

ENTRY OF AMENDMENTS

The amendments to the claims above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, Applicants believe that the amendments do not raise new issues or require a further search. Applicants further submit pursuant to 37 C.F. R. § 1.116, amendments after final presenting rejected claims in better condition for allowance may be admitted.

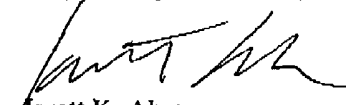
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CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,

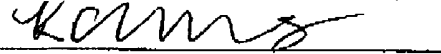


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Katie A. Chung
Date of Signature: June 11, 2004